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SIPDIS

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TAGS: [KIPR](#) [ETRD](#) [ECON](#) [LO](#)
SUBJECT: PATENT PROTECTION THREATENED BY PROPOSAL IN
PARLIAMENT

11. Summary and Action Recommendation - An amendment designed to overturn pharmaceutical patent legislation approved last Spring passed the first reading in the Slovak Parliament on March 20. The measure, introduced by an MP with significant generic pharmaceutical business interests, will be reviewed by the Slovak government and the relevant Parliamentary committees before being considered again by the Parliament in May. Post will continue to work closely with local pharma companies to ensure that the recent improvements in pharmaceutical patent protection, which led to Slovakia being removed from the 2006 Special 301 Watch list, are not undone through this amendment. State and Commerce can assist this effort by raising the issue with Slovak Economy Minister Lubomir Jahnatek during his April 3 and 4 visit to Washington. End Summary.

12. On March 20 the Slovak Parliament approved in the first reading an amendment to the Medicines Act proposed by MP Ivan Varga from the leading coalition party, Smer (Direction). The amendment proposes to overturn legislation passed in May, 2006, that established a formal link between the Drug Control Authority (SUKL) and the Industrial Property Office (Patent Office) to ensure that patent-infringing drugs would not be given market access. We fought hard to obtain the May 2006 changes. The lack of patent linkage was a key reason Slovakia had remained on the Special 301 Watch List for several years. Due to progress made towards implementing the patent linkage provision last Spring, as well as other GOS measures to enhance the protection of IPR, Slovakia was not included on the 2006 Watch List. In addition, no industry associations or individual companies recommended Slovakia for inclusion in the 2007 Special 301 Review.

13. The Varga amendment claims that the provision in Article 21a (8) g) from the Medicines Act, as amended in May, 2006, does not comply with Article 26 of the EU Directive 2004/27/EC relating to reasons for refusing a marketing authorization. This new amendment proposes to eliminate a sentence from the Medicines Act that requires SUKL to 'refuse' a generic registration if a valid patent still exists. The implementing regulations issued by the Health Minister in July 2006 had already clarified this point by noting that SUKL will not deny registration due to the existence of a valid patent, but will tie the final market authorization to the date of patent expiration. This was designed to appease concerns by the generic companies that they would not be able to take the necessary steps to register a drug (equivalency studies, etc.) in advance of patent expiration.

¶4. Ivan Varga had a lead role in trying to stop the 2006 legislation from passing. At the time he used many of the same arguments that are outlined in this current amendment. In addition to his current legislative efforts, Varga has also lodged a complaint with the European Commission, asking them to comment on the 2006 amendment. The EC provided a series of questions to the Ministry of Health based on these complaints, to which MOH replied in early March. Varga has ownership interests in at least three generic manufacturers in Slovakia including Biotika Slovenska Lupca and Slovakofarma Hlohovec, which he helped to privatize in the 1990's, as well as Zentiva. His companies have benefited in the past from the previous lack of adequate patent linkage in Slovakia by introducing generic equivalents of patent protected drugs to the marketplace.

¶5. Post was aware that the Slovak generic industry remained interested in overturning the patent linkage legislation. Ambassador has raised this concern each time he has met with Health Minister Ivan Valentovic, most recently during a February 2007 meeting. Although the legislation was proposed independently from the Health Ministry, a point that was stressed to EconOff by MOH officials on 3/21, Valentovic will have a lead role in both providing GOS comments on this legislation and leading the debate over the amendment in the Parliamentary Health Care Committee. The Ambassador sent Valentovic a letter March 22 outlining our concerns and encouraging the Minister to take action to ensure that patent protection is noted undermined. With the amendment having passed first reading, the government and separately each of the assigned Parliamentary committees (this includes the Health Care, Constitutional and Legal and Agricultural committees) have 30 days to provide comments. The Health Care committee will submit a combined report by May 4 to the Parliament.

¶6. Comment - As we did last Spring in support of the amendment that established patent linkage, Post will continue to work closely with AmCham's Local Area Working Group (LAWG) to ensure that this new amendment is not successful. The first step is to get the Smer-led government on board with our efforts. Slovak Economy Minister Lubomir Jahodatek's meetings with Commerce U/S Lavin on April 4 and State EEB A/S Sullivan on April 3 (to be confirmed) offer excellent opportunities to follow up on the Ambassador's letter to the Health Minister by stressing to Jahodatek the importance of IPR protection. Defeating this measure will also require significant outreach to ruling and opposition political parties. End Comment.
VALLEE